



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEE

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

DATE OUT: 22 / MARCH / 2012

SUBJECT: PRODUCT CHEMISTRY REVIEW OF MP [X] EP []
DP BARCODE No.: DP398272 EPA Reg. No.: 5481-9022
PRODUCT NAME: Def Technical Defoliant
COMPANY: AMVAC Chemical Corporation
FOOD USE [] INTEGRATED FORMULATION [X]
PCC: 074801 Decision No. 458243
ACTION CODE: R340 PESTICIDAL USE: Cotton Defoliant

FROM: Hari Mukhoty
Product Chemistry Team
Technical Review Branch / RD (7505P)

TO: Junita Gilchrist / Kable Davis, RM 25
Herbicide Branch / RD (7505P)

[Handwritten signatures and date]
3/22/12

INTRODUCTION:

The Registrant has submitted one amended CSF (dated: 01/30/2012) for alternate formulation (Alt # 2) to the basic product registered under EPA Reg. No. 5481-9022. The product chemistry data from five batch analysis for the proposed alternate formulation # 2 from a new manufacturing site [REDACTED] have been submitted under MRID: 486768-01. No other Group A data was submitted in the aforesaid MRID. However, the registrant cited data in the data matrix that were generated in Bayer Laboratory in USA (previous registrant) to support the registration of Basic product used by Bayer. Therefore, the reviewer called the registrant and explained the product chemistry data requirements for registration of the proposed alternate formulation on March 4, 2012. Then again, following a request from the PM, the reviewer sends an e-mail detailing the data requirements for the registration of the proposed alternate. As of this writing, TRB received no response from the applicant. Therefore, TRB decided to review the data to close the file.

The product chemistry data for the basic product were reviewed and accepted by PRB (SRRD) on 08/26/2003. The product label was accepted on 08/10/2010.

The aforesaid proposed alternate formulation (alt # 2) is manufactured by [REDACTED] for AMVAC Chemical Corporation in CA, USA.

The label text of the proposed label clearly indicates that this proposed alternate # 2 is intended to be formulated into a defoliant for use on cotton.

TRB has been requested to evaluate the product chemistry data required for the registration of the proposed Alternate formulation.

SUMMARY OF FINDINGS:

1. The proposed TGAI/MUP contains the active ingredient: S,S,S-Tributyl phosphoro-trithioate (97.9%).

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2. The overall mean of the active ingredient from the five batch analysis is 97.34% [MRID: 486768-01, Page 7 of 97]. This does not reflect the proposed nominal concentration of the active in the submitted CSF or the label claim in the accepted label.
3. The data submitted in the CSF does not match with the data from the five batch analysis tabulated in Table 6 in page 16 of MRID: 486768-01.
4. TRB has received the only Preliminary analysis data in MRID: 486768-01. All other Group A data are required for registration of proposed alternate formulation. Group B data are not required for alternate formulation.
5. The active ingredient and associated impurities were quantified by Gas Chromatography equipped with a Flame Ionization Detector (FID). Karl Fisher Titrator was used to quantify water content. The method was validated for selectivity, linearity & range, precision and repeatability and accuracy (Spike Recovery).

Similar analytical techniques can also be applied for Enforcement Analytical Method.

CONCLUSIONS:

1. TRB has reviewed the CSF (dated: 01/30/2012) for the proposed alternate formulation (2) and has found it to be unacceptable because (a). complete Group A data were not provided to TRB (b). the data recorded in the five batch analysis do not match with the submitted CSF. The CSF and the five batch analysis results are attached with this review and can be located in OPPIN CHEM DOCS.
2. If the starting material (830.1600) and the production process (830.1620) are identical to previously submitted data, the applicant must provide the certified statement to that effect and the MRIDs.

